



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA INT'L FEDERAL EXPRESS**

June 25, 2001

Our Reference: 2954512

George L. Gosden, Owner  
Sea Food World  
674 Harmon Loop Road, Suite 111-229  
Dededo, Guam 96912

**WARNING LETTER**

Dear Mr. Gosden:

On April 12 and 16, 2001, we inspected your seafood facility located at 118 Marine Drive, Unit C1, Eon Building, Dededo, Guam to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your fresh tuna and marlin to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 (Inspectional Observations) and discussed them with Marc F. G. Cruz, Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. The deviations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan to control the food safety hazard of histamine formation as a result of time/temperature abuse in fresh tuna and marlin received directly from the harvest vessel and from other distributors.
2. You must adequately monitor and document sanitation conditions and practices, to comply with 21 CFR 123.11(b) and (c). However, your firm did not monitor and maintain records related to the following areas of sanitation to ensure control:
  - a) Safety of water;
  - b) Condition and cleanliness of food contact surfaces;
  - c) Prevention of cross-contamination;
  - d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
  - e) Protection of food and food contact surfaces from adulterants;
  - f) Proper labeling and storage of toxic compounds;
  - g) Control of employee health conditions; and
  - h) Exclusion of pests from the processing area.

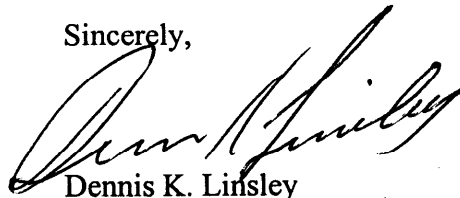
We may take further regulatory action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, HACCP plans, etc. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your seafood firm operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written over the printed name.

Dennis K. Linsley  
Director  
San Francisco District

Enclosure

cc: via Int'l Federal Express  
Marc F. G. Cruz, Manager  
Sea Food World  
118 Marine Drive, Unit C1  
Eon Building  
Dededo, Guam 96912